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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,651	12/06/2001	Harry R. Howard JR.	PC11839A	4848
23913	7590	12/16/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			RAO, DEEPAK R	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,651	HOWARD, HARRY R.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,23,25,27,28 and 30 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,23,25,27,28 and 30 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 4, 2004 has been entered.

Claims 22-23, 25, 27-28 and 30 are pending in this application.

Election/Restrictions

Applicants elected with traverse the invention of Group III, claims 22-23, 25, 27-28 and 30 (drawn to a therapeutic method comprising administering a compound of formula I) in Paper No. 6. Applicants also elected the species of (a) [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine as the SRI antidepressant and (b) ziprasidone as the atypical antipsychotic compound is acknowledged. The elected species were found in the prior art search and as per the guidelines above, the examination was limited to the elected species. All other SRI antidepressant and atypical antipsychotic compounds of claims 22-23, 25-28 and 30 are withdrawn from further consideration by the examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected species.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-23, 25, 27-28 and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over [Elliott et al., WO 00/50380 in view of The Merck Manual of Diagnosis and Therapy (1999)] in combination with [Busch et al., WO 97/42190 or Urban, U.S. Patent No. 5,359,068], in view of Preskorn, Outpatient Management of Depression (1999) (see http://www.preskorn.com/books/omd_s11.html).

Elliott (WO'380) teaches the use of an effective amount of the compound, [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine for the treatment of depression, anxiety disorders, obsessive disorders, etc., see the compound at page 7, line 33 and the therapeutic use in page 3, lines 11-32. The Merck Manual teaches an effective amount of a selective serotonin reuptake inhibitors as 20mg/day ~ 100mg/day.

Elliott reference does not teach the combination of atypical antipsychotic agent ziprasidone with the SRI antidepressant [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine.

Busch (WO'190) teaches the use of the antipsychotic agent Ziprasidone for the treatment of various disorders including anxiety, see page 1, lines 12-13. Busch teaches a recommended dosing range of 5-300mg/day, see page 6. Also, Urban (US'068) discloses ziprasidone (see Example 8) and the therapeutic use in treating anxiety, using the effective amount of the compound in the range of 5 to 500mg/day, see col. 11.

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Preskorn in the analogous art, teaches a combination treatment using antidepressants and antipsychotics (see the reference).

One of ordinary skill in the art would have been motivated to combine the reference teachings by selecting the two compounds independently taught in the references in a single therapeutic administration because the skilled artisan would have expected the combination to have the same properties and activity taught for the individual compounds as both the compounds are taught to exhibit similar properties. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that Elliott et al., do not disclose or suggest combining an atypical antipsychotic with an SRI antidepressant, 'wherein each of the atypical antipsychotic agent and the SRI antidepressant are administered in an amount from 0.05mg/day to 1500mg/day'. However, as indicated above, Elliott et al., teaches the use of SRI antidepressants in treating depression, anxiety, etc. and the Merck Manual provides a typical dose range for the antidepressant compounds. Busch and Urban individually teach atypical antipsychotics in the treatment of disorders including anxiety and the corresponding effective amounts of the compounds used. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful **for the same purpose**, in order to form a third composition to be used for the very same purpose." See MPEP § 2144.06. Furthermore, Preskorn teaches the combined treatment using antidepressants plus antipsychotics.

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Absent evidence to the contrary, possessing the teachings of cited prior art, one of ordinary skill in the art would have been motivated to employ the herein claimed agents into a single composition for the claimed treatment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

Deepak Rao
Primary Examiner
Art Unit 1624

December 12, 2004